

Guideline for Collection, Processing & Use of Convalescent Plasma (CP) for Experimental Treatment of COVID-19

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A. BACKGROUND

1. COVID-19 is an emerging infectious disease, caused by a novel coronavirus, now named SARS-CoV-2. It emerged in Wuhan city, Hubei province, China in December 2019.
2. This operational guide is based on World Health Organisation (WHO) Blood Regulators Network's Position Paper on "Use of Convalescent Plasma, Serum or Immune Globulin Concentrates as an Element in Response to an Emerging Virus" ¹ and also the Food and Drug Administration (FDA) paper on "Investigational COVID-19 Convalescent Plasma Guidance for Industry"².
3. Convalescent plasma (CP) has been used in a number of emerging infections for which there are no proven antivirals, including SARS, MERS, and Ebola virus disease (EVD). It may also be a potentially effective treatment strategy for COVID-19 disease.
4. In a meta-analysis of CP and hyperimmune globulin for Severe Acute Respiratory Infection (SARI) of viral aetiology, 32 studies on SARS and severe influenza showed a statistically significant reduction in the pooled odds of mortality following treatment compared with placebo or no therapy (odds ratio, 0.25; 95% confidence interval, 0.14–0.45). Notably there were 699 treated and 568 untreated SARS patients from 8 observational studies with absolute risk reduction in mortality ranging from 7-23%³.
5. The H1N1 influenza virus pandemic in 2009-2010 had seen the use of convalescent serum obtained from apheresis donation used to treat individuals with severe H1N1 2009 infection requiring intensive care which had resulted in reduced respiratory viral burden, cytokines responses and mortality⁴. During Avian flu outbreaks of H5N1⁵ and H7N9⁶ physicians also had used convalescent sera resulting in all patients surviving the infections.
6. These pivotal historical precedents provide reassuring experiences in dealing with COVID-19 pandemic right now despite limited data that support the effectiveness of convalescent serum COVID-19. There are few reports that convalescent serum was used for therapy of patients with COVID-19 in China during the current outbreak⁷ and few others available information suggest that convalescent serum administration may help to reduce viral load and was a safe option.
7. CP donor selection, collection and processing should follow the same principles for voluntary non-remunerated blood donation, to ensure donor's health and recipient safety. However, in light of the potentially life-saving impact of these specific donations, consideration may be given to assess the risk reduction value of donor selection criteria against the risk impact of excluding the donor.
8. In order to minimise any adverse impact of donor perceptions and fears regarding COVID-19 (SARS-CoV-2), it is proposed that the donor selection, collection, donation

testing of the convalescent plasma and storage of CP to be performed at the blood collection centres in Malaysia with an access to apheresis donation service.

9. Although Convalescent Whole Blood (CWB) or CP may be used for treatment, it is proposed that only CP to be collected by apheresis method. This enables a higher volume of plasma to be obtained from the donor, thus providing the patient with only the component required.
10. Furthermore, CP donation allow a minimum inter-donation interval of 2 weeks from prior donation, provided the serum total protein and albumin level is within normal limits, as compared to 12-16 weeks for CWB.
11. CP donors are defined as individuals who have fully recovered clinically from COVID-19 infection, and tested negative for SARS-CoV-2 by PCR method. Clinical recovery for symptomatic patient is defines as resolution of fever without antipyretics for a minimum of 24 hours and improvement in respiratory symptoms such as cough or shortness of breath for at least 10 days. Whereas for asymptomatic patient, the criteria for clinical recovery is 10 days after the first positive oropharyngeal (OP) or nasopharyngeal (NP) swab. These patients are able to be discharged without requiring retesting.⁸ The general workflow for COVID-19 CP donation, processing and use is diagrammed in Appendix 1.
12. At the time of the writing, one company is gearing up to generate antibody preparations against SARS2-CoV-2 from COVID-19 convalescent sera⁹. Undoubtedly having a highly purified and high titre of antibodies against COVID-19 is preferable to convalescent plasma however, such preparations will not be available for many months, whereas locally produced convalescent plasma can be made available much sooner.
13. This guideline is divided into 3 sections:
 - I. Section B is on the selection of potential CP donor by the attending physician.
 - II. Section C, D and E are on the process of donation of convalescent plasma at the Pusat Darah Negara (PDN) and other blood centres.
 - III. Section F is on the use of convalescent plasma in the management of COVID-19 patients.

B. SELECTION OF POTENTIAL CONVALESCENT PLASMA DONOR

1. **General criteria:** Blood donor selection and qualification will follow standard criteria for code of ethics for blood donation and Donor Eligibility Criteria according to Transfusion Practice Guidelines for Clinical and Laboratory Personnel 4th Edition 2016. Blood donor selection and qualification criteria are as below:
 - Age: 17 to 60 years old. For those 17 years old: require guardian/parental consent. Potential donors >60 years old: may be accepted if donor is certified by a physician to be medically fit to undergo blood donation after passing basic medical examination.
 - Weight: minimum weight 40kg **
 - Haemoglobin: 11 – 18 g/dL **
 - Blood pressure: Systolic 100 – 150 mmHg/ diastolic 70 – 100 mmHg.
 - Medical and medication history: (refer Guidelines for the Acceptance and Deferral of Donors)
 - Specific criteria for apheresis donor: Donor should have good venous access. The volume of donated plasma depends on the donor weight.
 - Malaysian citizens only who are able to understand, read and write in Bahasa Malaysia or English.
2. To widen the potential donor pool for CP, variations to standard criteria may be considered for age, weight and haemoglobin level of the donor. However, any variation should be determined only after a thorough medical assessment of the potential donor and with the agreement of the Infectious Disease Physician and Transfusion Medicine Physician.
3. **Selection of potential CP donor** should be based on the following clinical criteria:
 - Potential CP donors should fulfil the criteria for discharge (refer MOH COVID-19 Guidelines: Annex 2)⁸.
 - Physician should select potential CP donors that are clinically asymptomatic at least one (1) week after discharge and should be tested for COVID 19 Immunoglobulin (Ig) G antibody and other screening tests which are required as listed in point 5.
4. During selection, the potential CP donor will be counselled and explained regarding the donation of convalescent plasma. The attending physician should
 - Explain to the potential CP donor the possibility of collecting his/her plasma donation, emphasizing that this could be useful as an empirical treatment for the other COVID 19 patients.
 - Inform the potential CP donor that their donation is of voluntary basis and there will be no payment to them for their blood or plasma donation (non-remunerated).

- Explain that if the potential CP donor agrees for donation, he/she would be assessed for suitability to donate plasma by PDN/other blood centres.
 - Obtain a written informed consent from the potential CP donor for donation of convalescent plasma for transfusion (Appendix 2).
 - Maintain donor confidentiality to avoid any coercion to donate from the community.
5. To ensure that the CP is safe for the intended recipient and minimise the risk of collecting an unsuitable donation, the blood samples should be taken during selection from the potential CP donor and tested for the following as part of the CP donor selection process:
- Transfusion Transmitted Infection (TTI) screening, which includes: HIV, Hepatitis B, Hepatitis C and syphilis
 - Full blood count
 - Liver function test
 - COVID-19 antibody test

Refer to Appendix 3 for requirement of samples and forms.

6. **Review of results:** Physician should review the potential CP donors and all the screening results at least one (1) week after sending the samples. Only those who are tested negative for HIV, HCV, HBV and syphilis with a positive Ig G antibody for COVID-19 may be considered for CP donation.
7. **Referral to blood centre for CP donation:** Preferably, the potential CP donor may be referred to PDN/other blood centres for CP donation 28 days after discharge. However, in the event that CP needed to be collected earlier, potential CP donor may be considered if they had achieved complete resolution of symptoms at least 10 days prior to donation and should be tested positive for COVID 19 Ig G antibody after clinical recovery.
8. The potential CP donor will be informed and an appointment made for the collection of his/ her CP with the respective donation site. The attending physician should provide a referral letter (Appendix 4), with the following information:
- Clinical history.
 - Full Blood Count and LFT: albumin, total protein.
 - Result of screening for HIV, Hepatitis B, Hepatitis C and syphilis.
 - COVID-19 Ig G antibody result.
9. Final decision on the suitability of the potential donor for CP donation will be made by consensus between Infectious Disease Physician and Transfusion Medicine Physician.

** Relaxed criteria maybe given as potentially life-saving impact of these specific donations.

C. DONATION OF CONVALESCENT PLASMA

1. Blood collection and donor care

- The donor should be provided with good care before, during and after the plasma donation procedure.
- Any adverse donor reactions should be adequately and promptly managed and recorded
- The inter-donation interval for collection of plasma by apheresis should be 2 weeks
* If there is failure of return of 100mls red cells during apheresis, then there should be a minimum interval of 8 weeks before the plasmapheresis donation.
- Potential CP donors with abnormal TTI test results should be referred to appropriate health-care institutions for further investigation, confirmation, counselling, treatment and care following the existing guidelines.

2. Before the donation of CP, the donor should fill and sign the Blood Donor Registration Form (Appendix 5). The pre-donation counselling will be done by a qualified and competent medical doctor following the blood donation criteria practised at blood collection centre. The medical doctor should also review the referral letter, the COVID-19 PCR result at diagnosis, the COVID-19 antibody result at the time of selection to be a potential CP donor and the other screening results. In addition, the process of CP donation and potential adverse reactions should be explained to the potential donor. COVID-19 antibody test should be performed using rapid test kit (RTK) and only potential donor with positive Ig G may be considered to proceed with the CP donation.

3. The donor information will be registered into the Blood Bank Information System version 2 (BBIS2) under the donor management module. The donation type should be selected as convalescent plasma. The physical copy of the Blood Donor Registration Form, referral letter and CP donation consent will be kept in a secure manner (as for medical records) at the blood centre for confidentiality reasons. These physical forms will be maintained as per current guidelines.

4. CP will be collected from eligible donor by apheresis at the blood collection centres using any of the plasma apheresis machines (either the Autopheresis–C Plasmapheresis System (Auto C) or Haemonetics PCS2 Plasmapheresis System) or Trima Accel or any validated apheresis machine.

5. Infection control procedures and personal protective equipment (PPE) i.e. face shield, surgical facemask, gloves and plastic apron and disinfection procedures when handling donor samples and during CP collection will follow standard precautions for

blood-borne infections, even though the donor has already recovered from COVID-19.

6. Staff of the blood centre will perform the plasmapheresis procedure at a location where the donor can be monitored closely and where emergency equipment and personnel is available on hand. Medical management of the CP donor during the apheresis collection procedure will also be provided by the attending medical doctor in consultation with Transfusion Medicine Physician and the ID Physician.
7. Each CP unit will be labelled with barcode number to link donor, product and recipient for transfusion traceability. In addition, a unique "CP" label also placed on the blood donation form, tubes, and plasma blood bags to facilitate physical identification of CP products. The labelling of CP units will be performed by staff at the blood collection centre.
8. Additionally, five samples of blood should be collected and labelled with the unique barcode number and "CP" label before sending for the following test:
 - Serology testing for HIV -1 & 2 antibody, HCV antibody, Hepatitis B surface antigen, Treponemal pallidum antibody
 - 8mls in K2 EDTA (with gel) tube
 - Nucleic Acid Amplification (NAT) Test for HIV, HCV, HBV
 - 8mls in plain tube.
 - ABO Rh D Blood Grouping and irregular red cells antibody screening
 - 8mls in K2 EDTA tube
 - Antibody titration for COVID-19 to IMR or hospital microbiology laboratory
 - 8mls in plain tube
 - Anti-HLA antibodies test for multiparous female donor
 - 6mls in K2 EDTA tube
 - 6mls in plain tube

D. SCREENING OF CONVALESCENT PLASMA

1. Screening of the donated unit for TTI will be conducted at NBC for the following tests according to the national policies for blood donation screening:
 - a. Serological testing for HIV-1&2 antibody, HCV antibody, Hepatitis B surface antigen and RPR
 - b. Nucleic Acid Testing (NAT) for HIV, HCV, and HBV
2. Screening for TTI will be conducted on a separate assay run from normal collection. Serological and molecular tests for HIV/HBV/HCV will be performed using the current analyser respectively. Only donations which were tested negative for the blood borne infections listed will be accepted for use as CP.
3. The Immunohaematology laboratory will conduct testing for donor regrouping for ABO and RhD. In addition to the donor regrouping testing, irregular red cell antibody screening will be conducted.
4. If the red cell antibody screening result is positive, further investigation will be carried out by the blood centre. The CP with positive antibody may be transfused to the patient with negative corresponding antigen if required.
5. Infection control procedures for laboratory officers handling the donor samples and performing the testing will follow the standard precautions for blood-borne infections when handling clinical samples.
6. Decontamination procedures after testing and following blood spills will follow the standard laboratory safety protocols for blood-borne infections. Further advice, if necessary, on precautions may be sought from ID physicians on the handling of the blood samples from the CP donors, as the need arises.
7. Furthermore, the antibody titration for COVID-19 should be send to the appropriate MOH laboratory that provide the service such as Institute of Medical Research (IMR) or the hospital microbiology laboratory. The antibody titration should be conducted to quantify the antibody content in the CP.

E. STORAGE, SUPPLY AND TRANSPORT OF CP UNITS

1. The donated convalescent plasma will be processed within 24 hours of collection.
2. The CP will be split into 2 bags if total CP volume is ~500mL. The units will be quarantined while waiting for TTI result at or below -25°C.
3. Inventory management of the CP units will be handled to minimise expiry.
4. Each CP unit will be stored in ~200-250 mL volume. The CP units will be stored at the blood centres in a separate designated blood bank freezer for up to 24 months.
5. When request for CP plasma received, the appropriate ABO matched CP units for transfusion will be selected.
6. Transportation of CP units to requesting hospital should be according to standard protocols and cold chain should be maintained as to preserve the integrity of the unit until it reaches the recipient. If the CP are transported as liquid plasma in which the temperature is maintained between 2-6°C, it can be stored up to 40 days. Alternatively, if the CP are transported in frozen state, below -25 °C, it can be stored up to 24 months¹.

F. SELECTION OF RECIPIENT FOR CP TRANSFUSION AND MONITORING

1. The selection of patient for CP transfusion and management of the transfusion will be determined by the attending ID physician and/or ICU physicians. Approval for release of CP transfusion should be made by attending physician in discussion with the Transfusion Medicine team.

2. The indication of CP administration is adapted from WHO severe disease criteria and Arabi et. al.¹⁰ as follow:

- Laboratory-confirmed COVID-19 Infection, AND I) or II):

I. Severe or Critical illness as defined by WHO criteria:

- Dyspnea
- RR>30/mi;
- SaO₂ <93%
- P/F ratio <300
- Lung infiltrates >50% of lung fields within 24-48 hours (if available).

Other criteria:

- Admission to an ICU
OR
- Current receipt of mechanical invasive or non-invasive ventilation **OR**
- current receipt of intravenous vasoactive medications to maintain mean arterial pressure (MAP) >65 mmHg
OR
- Myocarditis/ Myocardial dysfunction secondary to SARS-CoV-2 **OR**
- Haemophagocytic lymphohistiocytosis (HLH) secondary to SARS-COV2. (if available)

II. Predicted progression to severe illness as defined by;

Need for supplemental oxygen/ dyspnea/ respiratory rate >20/min **AND** one of the followings:

- Marked lymphopenia (<0.6 x 10⁹/L)
- Neutrophilia (>4.0 x 10⁹/L)
- Worsening thrombocytopenia (<100 x 10⁹/L)
- Markedly raised and increasing levels of CRP (>60mg/L)
- LDH (>1000 U/L)
- Ferritin (>3000 mcg/L)
- Progressive lung infiltrates, or a validated predictive model.

3. Any deviation from the above indications should require approval from the ID Physician, Transfusion Medicine Physician, head of Medical Department and Hospital Director.
4. The following are the exclusion criteria for CP transfusion:
 - History of severe/life threatening allergic reaction to blood or plasma products
 - Known IgA deficiency (IgA levels should be checked prior to transfusion, levels should not below the reference interval).
5. The consent for CP transfusion should be obtained from a patient that is planned for CP transfusion. The attending physician should be responsible for taking informed consent from the recipient of CP before giving the CP. The consent should not only follow the national standard of blood transfusion consent, but also the indication for novel therapeutic usage in COVID-19.
6. The selection of the appropriate ABO specific plasma units for CP transfusion would be made by Transfusion Medicine Physician.
7. The standard dose of CP for adults to be administered approximately 200-250ml as a single dose over 1-2 hours. The dose of CP for children is 4-5 ml/kg as a single dose over 1-2 hours.
8. Data collection on patient demographics, clinical progression, and outcome should be done by the treating physician and the analysis should be done by Transfusion Medicine Physician. Data collection fields will include the data points as outlined in Appendix 7.
9. In the event of ethical issues or dilemma arising from this CP transfusion (i.e.: recipient selection in the event of CP unit shortage) CP ethics committee may be formed according to the local setting

G. CONVALESCENT PLASMA QUALITY PROCEDURES

1. Referring for Convalescent Plasma Donation

No.	Activities	Responsibility
1.1	<p>Infectious Disease (ID) Physician to counsel, identify and discuss with potential CP donor regarding the risks and benefits of plasmapheresis donation and that</p> <ul style="list-style-type: none"> • The purpose of plasmapheresis as empirical treatment for COVID-19 infections. • The procedure for plasmapheresis including performing TTI screening on the potential CP donor sample. • Provide a referral letter together with a copy of the signed consent forms 1 & 2, the TTI screening results, haematology and biochemistry results (whenever possible). • Following consent, to provide the contact detail of the potential donor to the liaison officer in the blood centre. 	ID Physician Transfusion Medicine Physician
1.2	<p>Proceed for plasmapheresis donation if</p> <ul style="list-style-type: none"> ➤ All the TTI screening are negative or non-reactive. ➤ Acceptable value of Haemoglobin, albumin and globulin. ➤ COVID-19 IgG is positive. 	ID Physician Transfusion Medicine Physician
1.3	<p>Approve the convalescent apheresis plasma donation based on the following factors:</p> <ul style="list-style-type: none"> • Diagnosis • Date of recovery • Potential CP donor's clinical condition and underlying medical condition. • To perform/inquire the ID Physician the following blood tests prior to donation: <ul style="list-style-type: none"> ➤ Full blood count (FBC) ➤ Biochemistry test: albumin and total protein, calcium (if available). ➤ COVID-19 antibody test 	Transfusion Medicine Physician

	<ul style="list-style-type: none"> ● Established potential CP donor status with regard to TTI screening markers before making the final decision: <ul style="list-style-type: none"> ➤ Anti-HIV 1 and 2 ➤ HBs Ag ➤ Anti HCV ➤ Syphilis 	
1.4	Inform the referring ID physician and/or of the date of the plasmapheresis	Transfusion Medicine Physician
1.5	Inform the respective divisions namely Blood Procurement, Transfusion Microbiology Laboratory, Immunohematology, Production Section and Blood Supply Management Section on the date of the plasmapheresis donation.	Assigned Medical Officer

2. Convalescent Plasma Pre-Donation Registration and Counselling

No	Activities	Responsibility
2.1	Identify the potential CP donor when they come to the PDN for the first time. To call for collection team activation alert. Donor will be usher to special counselling room.	PDN counter staff
2.2	Register donor in BBIS2-Donor Management module. <ul style="list-style-type: none"> ● Note: To register as a convalescent plasma donor, performs ABO blood grouping, haemoglobin estimation and COVID-19 antibody test using the RTK. ● To provide number barcode and CP unique labels. ● Open a “Convalescent Plasma Donation” file. (Refer PDN/BP/QP-03: Apheresis Donation)	PDN counter staff
2.3	Paste pink coloured convalescent plasma (CP) label onto: <ul style="list-style-type: none"> ● Donor Certificate Booklet (PPDK 9-Pin.3/97) ● Donor Registration Form (PDN 3/2014) 	PDN counter staff

	<ul style="list-style-type: none"> ● “Convalescent Plasma Donation” file. 							
2.4	<p>Assigned Transfusion Medicine Physician review all related documents:</p> <ul style="list-style-type: none"> ● Referral letter ● Copy of signed consent forms 1 & 2 ● Copy of TTI screening results 	Assigned Transfusion Medicine Physician						
2.5	Assigned oncall team to counsel the donor.	Assigned Transfusion Medicine Physician						
2.6	<p>Explain to the potential CP donor regarding the process of apheresis donation and assess the eligibility of blood donation.</p> <p>Note: Relaxed criteria maybe given as potentially life-saving impact of these specific donations.</p>	Assigned Transfusion Medicine Physician						
2.7	<p>Decide on the volume to be collected, taking into consideration the venous access of the patient.</p> <table border="1" data-bbox="331 1249 1114 1469"> <thead> <tr> <th>Weight (kg)</th> <th>Volume to be collected</th> </tr> </thead> <tbody> <tr> <td>40 – 50</td> <td>250 ml</td> </tr> <tr> <td>> 51</td> <td>500 ml</td> </tr> </tbody> </table>	Weight (kg)	Volume to be collected	40 – 50	250 ml	> 51	500 ml	Assigned Transfusion Medicine Physician
Weight (kg)	Volume to be collected							
40 – 50	250 ml							
> 51	500 ml							
2.8	<p>Proceed if potential CP donor is eligible and agrees with the donation and to sign:</p> <ul style="list-style-type: none"> ● Blood Donor Registration Form 	Assigned Transfusion Medicine Physician						
2.9	Donor will be advised on fluid intake and Confidential Unit Exclusion	Assigned Transfusion Medicine Physician						

2.10	File all the necessary documents, including the referral letter and the investigations results into the donor's "Convalescent Plasma Donation" file.	Assigned Transfusion Medicine Physician
2.11	Send the donor to the donation room with the "Convalescent Plasma Donation" file, Donor Registration Form (PDN 3/2014) and dedicated donation barcode.	Assigned Transfusion Medicine Physician
2.12	If the donor is not eligible to donate according to guidelines set up by the PDN: <ul style="list-style-type: none"> ● Inform the donor and note the reason of deferral on the donation card and donation book ● Refer the donor back to the referring clinician 	Assigned Transfusion Medicine Physician

3. Convalescent Plasma Donation

3.1	Collect plasma according procedure. Refer PDN/BP/QP-03 – Apheresis Donation and Appendix 6. Note: -Stick the pink coloured CP labels onto the blood bag and all tubes. -To take 2 extra samples for antibody titration for COVID-19 and send to Transfusion Microbiology Laboratory (TML). - Anti-HLA antibodies (for multiparous female donor) and send to Histocompatibility and Immunology Laboratory (H&I).	Sister / SN / CN Bleeding Unit
3.2	Inform TML, Production Section, Blood Supply Management Section, H&I and/or Clinical Transfusion Laboratory (for HKL, HTA) by filling up Convalescent Plasma Donation Form. Note to respective laboratory senior MLTs regarding the special products.	Assigned Medical Officer

4. Quarantine of Convalescent Plasma

4.1	<p>The donation samples are received at Receiving Bay for tally procedure. The donation samples will be collected by PPK TML and IH for testing.</p> <p>Refer PDN/CP/QP-03- Receiving of Samples at Receiving Bay.</p> <p>Note: PPK TML to take the TTI screening and antibody titration for COVID-19 samples.</p>	PPK/MLT Production Section
4.2	<p>Collected convalescent plasma is received by Production Laboratory for processing and quarantine procedure. Refer PDN/CP/WI-01- Receiving and Labelling of Pre-Screened Blood and Apheresis Donations.</p> <p>Note: To split unscreened convalescent plasma into two units if collected volume is between 500mL.</p>	MLT Production Section
4.3	<p>Freeze the unscreened convalescent plasma in a dedicated plasma freezer at below -25°C.</p>	MLT Production Section
4.4	<p>Receive notification of non-reactive confirmation results from TML. Retrieve convalescent apheresis plasma to be released from quarantine storage for post screen labeling and to issue CP to Blood Supply Management Section.</p>	MLT Production Section

5. Storage of Convalescent Apheresis Plasma

5.1	<p>Convalescent apheresis plasma stored in dedicated plasma freezer. Refer PDN/BI/WI-06 "Storage of Blood and Blood Component"</p> <p>*To label the dedicated freezer compartment with "Convalescent apheresis plasma"</p>	MLT Blood Supply Management Section
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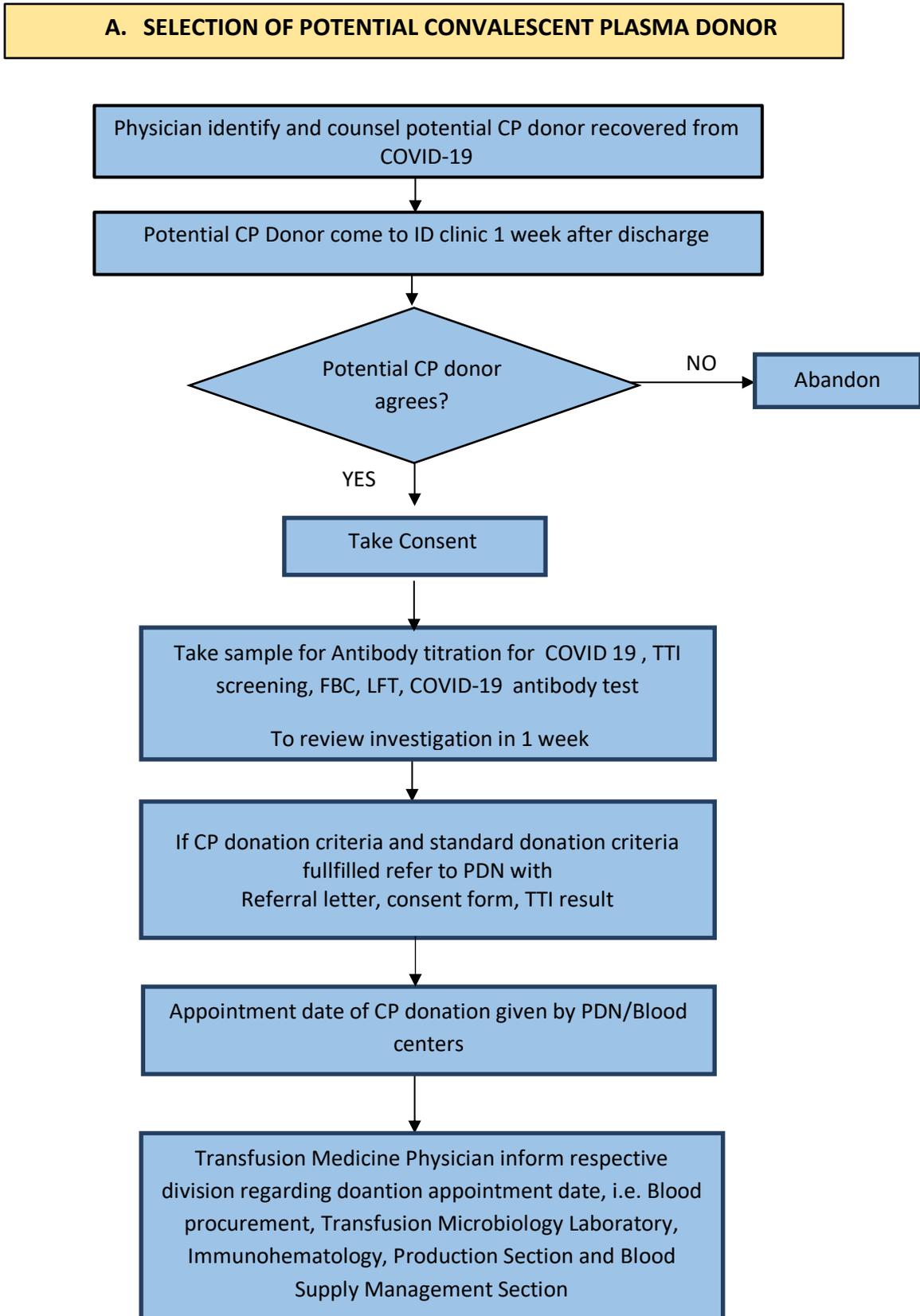
6. Supply of Convalescent Plasma Apheresis

6.1	<p>Request of convalescent plasma made by clinician to Transfusion Medicine Physician /MO on call. Establish:</p> <ul style="list-style-type: none"> • Name, IC, RN of patient • Ward • Diagnosis and infection history • Convalescent apheresis plasma volume and frequency dose • ABO blood group • Clinician contact detail 	MO/Transfusion Medicine Physician
6.2	<p>Give CODE for transfusion if clinically indicated after approval by Specialist and Consultant. Inform the Blood Supply Management Section for issuing and supply.</p>	MO/Transfusion Medicine Physician
6.3	<p>Received request form from Hospital and prepare the convalescent apheresis plasma. Refer PDN/BI/WI-07- "Release Request For Blood Component".</p>	MLT Blood Supply Management
6.4	<p>To supply the convalescent apheresis plasma to Hospital Blood Porter/PPK or Clinical Transfusion Laboratory, NBC. Refer PDN/TL/WI-03- "Handling of component request"</p>	PPK/MLT Blood Supply Management Section,
6.5	<p>To issue the convalescent apheresis plasma to Hospital Kuala Lumpur.</p>	MLT CTD

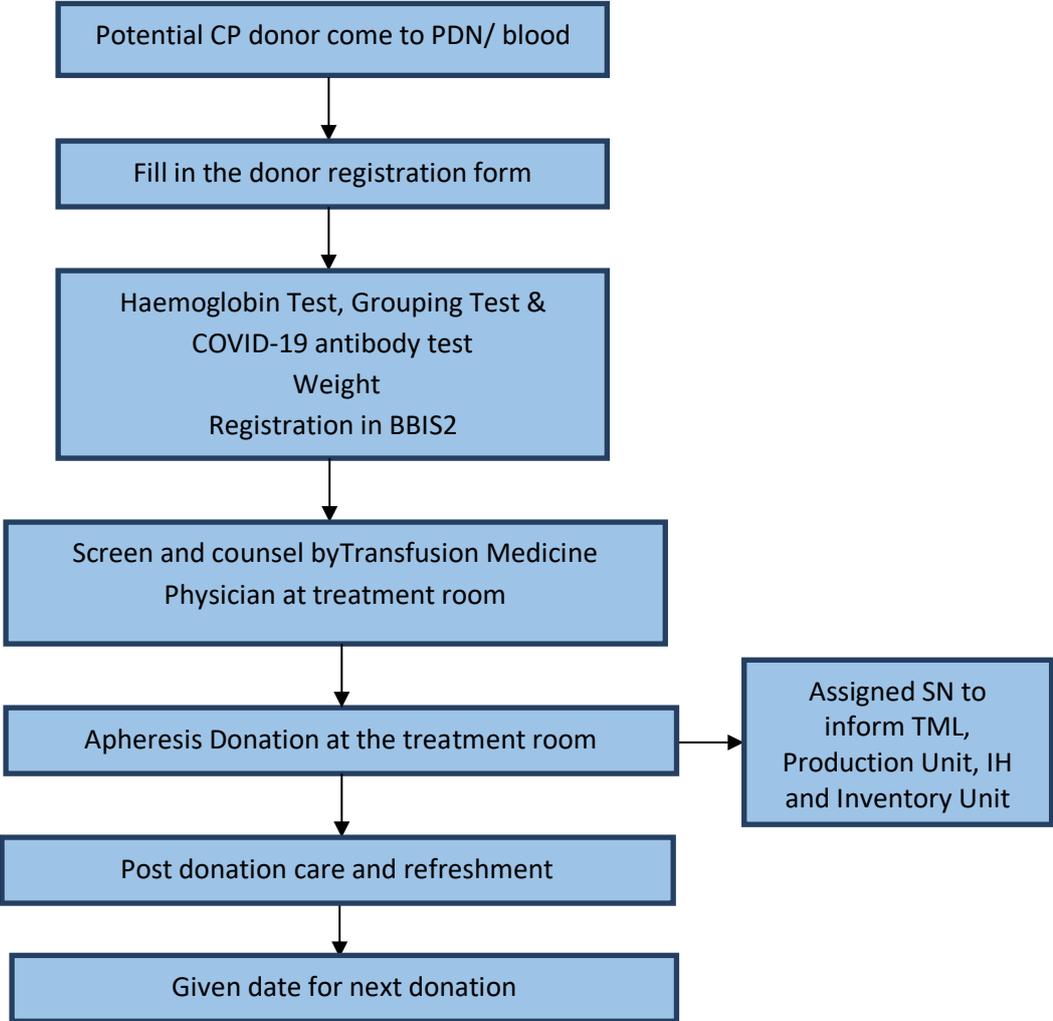
H. REFERENCES

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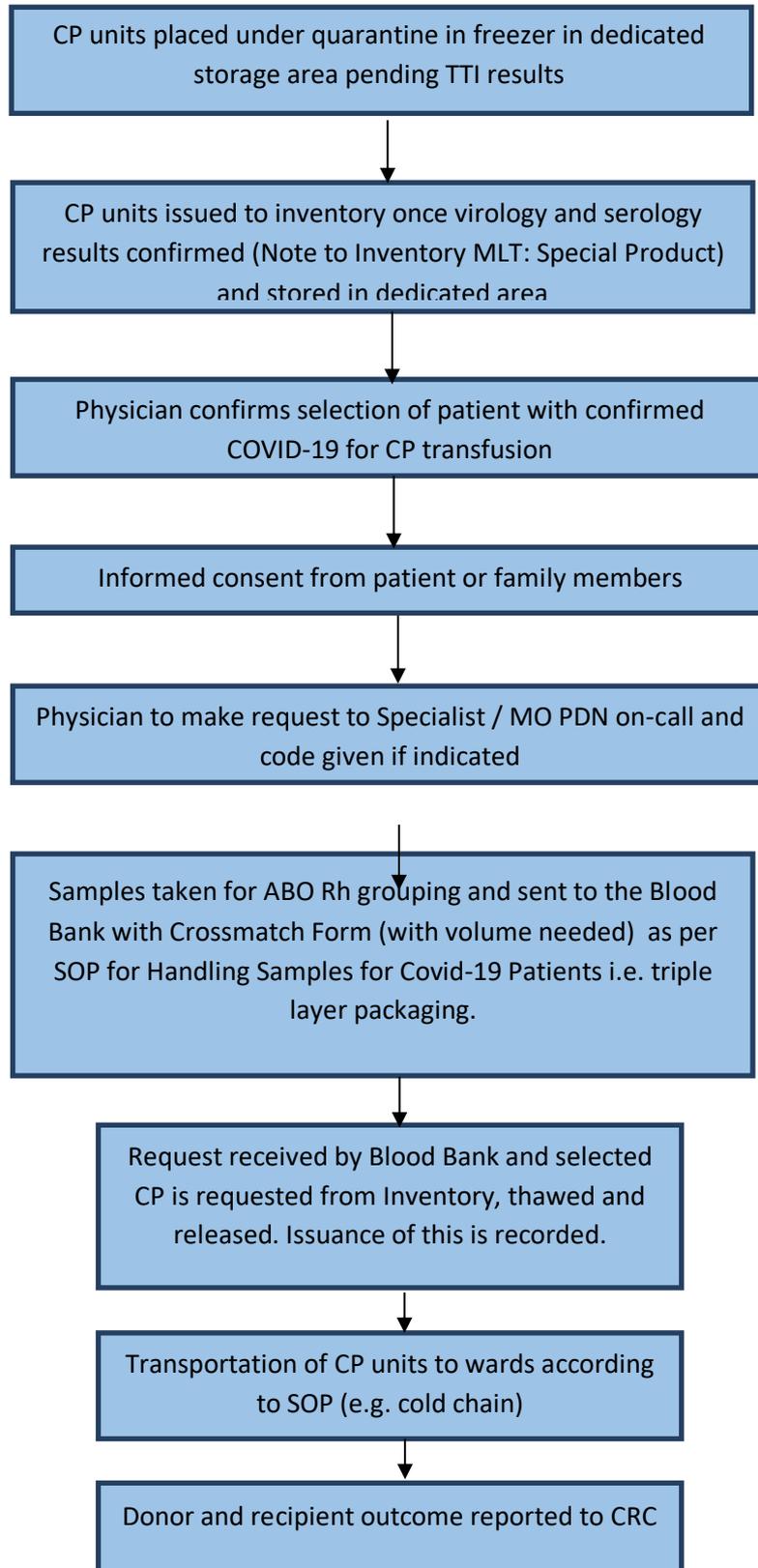
Flowchart of Convalescent Apheresis Plasma Collection from Patient Recovered from COVID-19



B. DONATION OF CONVALESCENT PLASMA



C. SUPPLY OF CONVALESCENT PLASMA (CP)



Consent Form and Information Booklet

	Name: NRIC: DOB:
Donation of convalescent plasma to treat COVID-19 infection Procedure Information Sheet	Race: Sex: Case No:

What is donation of convalescent plasma?

COVID-19 is an infectious disease, caused by a novel coronavirus, now named SARS-CoV-2. It emerged in Wuhan city, Hubei province, China in December 2019. COVID-19 infection spreads primarily through droplets of saliva or nasal discharge and can cause wide spectrum of symptomatic infection ranges from mild to critical with multiple organ failure, with a death rate of over 2.3%

Except for some experimental treatments, no treatment or vaccine is currently available or proven to be effective. People like you, who have recovered from COVID-19, did so because your body was able to fight and overcome the disease, and now your blood contains substances called antibodies which are capable of fighting the COVID-19 virus.

Convalescent plasma (CP) is a potentially effective treatment strategy for novel coronavirus and it has been used in a number of emerging infections for which there are no proven antivirals, such as SARS, MERS, and Ebola virus disease (EVD).

Why am I requested to undergo this procedure?

We think that some of the currently infected patients could be more likely to recover if they receive some of your plasma (the liquid part of your blood). But we don't know this for sure. It is possible that a patient with COVID-19 may not recover, even after receiving your plasma. Because we don't have any other proven treatment options at present, we would like to try it, in case it is successful, as it has been for certain other viruses. You could think of this as a gift to another person.

Please be assured that blood donation, including plasma donation, is voluntary and non-remunerated in Malaysia. You will not be forced to donate plasma if you are not agreeable.

What are the preparations?

We will first review the medical referral letter from the health facility/attending hospital that treated you for COVID-19 and conduct an assess to see if you can safely donate plasma. If you agree to donate plasma for COVID-19 treatment, we will first take a small amount of your blood (~32ml) to check your blood type and whether your blood can be used for COVID-19 treatment.

If your haemoglobin is too low or if you are not able to donate for any reason, we will not proceed but will explain to you if any medical follow up is needed. However, if you are suitable for donation, we will arrange a suitable date and time for the donation.

How is the procedure performed?

For the plasma donation, you will be asked to come to donation centre. Following registration and predonation check, an experienced nurse will insert a needle into your arm veins under local anaesthesia. The needle will be used to draw out your blood into a machine that will separate the plasma (liquid part of the blood) from the cellular part of the blood. After the separation step is done, your blood cells will be returned to you via the same needle. To stop the blood from clotting, a liquid blood thinner, known as anticoagulant, will be automatically mixed with the blood as it is pumped from the blood into the machine. About half a litre (eg a small mineral water bottle) of plasma will be collected, and the procedure takes 30-45 minutes.

What are the risks and complications of the procedure?

Taking blood from your arm may sometimes cause bruising, mild pain or discomfort and in very rarely, infection. We will take all precautions to minimize these risks.

Some people may feel light-headed or giddy when the needle is placed into their vein, during or after donating plasma. This lasts for a few minutes and will subside. You will be monitored closely throughout the procedure and encouraged to drink plenty of fluids at the end of the procedure.

Sometime with the use of anti-coagulant, you may feel a tingling sensation around your mouth and fingers. Some donors may experience muscle twitching. Please notify the nurse if any of these occur. You may be given some tablet of calcium supplements.

Overall, it is safe procedure in the vast majority of donors. However, other complications may rarely occur such as breakage of red cells, a heart rhythm abnormality or marked changes in blood pressure has been reported and requiring hospitalisation may rarely occur.

What do I expect after the procedure?

You will be given light refreshment after the procedure and you are expected to stay in the donation area for another 30 minutes. You can return to normal activities but try to avoid strenuous activities for the rest of the day. You should drink plenty of fluids over the next 24 hours. Your body will replace the lost fluid immediately.

The plasma that has been collected will be stored in a refrigerator or freezer. It will not have your name on it. When there is a patient with COVID-19 who is likely benefit from the use of plasma donated by you, it will be taken out of the stock, brought to room temperature, and given to the patient through vein. We will keep a close watch on the patient and record everything, so that we learn from the experience, and know more about its use for COVID-19 treatment.

What are the other options?

Not applicable.

What will happen if I do not undergo the procedure?

You are free to decide whether or not to donate blood or plasma. If you do not meet the donor suitability criteria, you will be immediately informed by the doctor in charge.

Once your blood and/or plasma has been collected, you can request that it be withdrawn at any time prior to it being transfused to a patient, by informing the attending doctor. After it has been given to a patient, you can no longer make this request.

Your decision to request that your donation be discarded if it has not yet been transfused, will not affect your future care.

Others questions that a donor may have

Confidentiality

Any information that you provide and all test results will be treated confidentially. The medical staff who test your blood have the responsibility to inform you of all the blood test results, and to advise you on any treatment they think you will require.

Will I know who will or has received my blood/plasma?

A patient with COVID-19 infection would receive your donated plasma, but it is difficult to predict exactly who will receive it. The person should have a compatible blood type to yours. The donated plasma will have a unique donation number but not your name, so no one will know whose plasma is given to the patient. Be assured it will be used for a patient who requires it, and all information about you and your donation will remain confidential.

Will the person who receives the blood/plasma know who provided it?

No one, including the patient who receives your donation will know who has provided it. This is so that your privacy is protected. Be assured that your donation will be treated with respect.

Expenses and payments

There will be no charges to you for any costs related to this donation. There will be no payment for you to participate in this donation either. If you have any questions, feel free to contact us at Pusat Darah Negara (Phone: 03-26132688)

	Name: NRIC: DOB:
Donation of convalescent plasma to treat COVID-19 infection Procedure Information Sheet	Race: Sex: Case No:

Acknowledgement

Part I-To Be Filled by Patient/Legal Guardian

I acknowledge that I have received this information sheet.

I acknowledge that the complication(s) listed are not exhaustive.

I understand that I will be given the opportunity to ask for more information about the procedure.

Acknowledged by:

.....
*Signature/right Thumb Print

.....
Date (dd/mm/yy)

.....
Name*Patient/Legal Guardian and IC number

Part II-To Be Filled by Medical Practitioner/Designate

I confirm that I have explained the reason for and the nature of the procedure and the potential complication(s) that may arise from the procedure to the patient/legal guardian.

.....
Name & signature of Medical Doctor and IC number

.....
Date (dd/mm/yy)

*please delete accordingly

Part III-To Be Filled by Transfusion Medicine Team

I confirm that I have explained the reason for and the nature of the procedure and the potential complication(s) that may arise from the procedure to the patient/legal guardian.

.....
Name & signature of Medical Doctor and IC number

.....
Date (dd/mm/yy)

	Nama: No K/P: Tarikh lahir::
Maklumat prosedur berkaitan pendermaan <i>convalescent plasma</i> untuk merawat infeksi COVID-19.	Bangsa: Jantina: No kes:

Apakah yang dimaksudkan dengan pendermaan *convalescent plasma*?

COVID-19 adalah penyakit berjangkit, yang disebabkan oleh coronavirus novel, iaitu SARS-CoV-2. Wabak ini pada mulanya dikesan pada pertengahan Disember 2019 di Bandaraya Wuhan, Hubei, China. Jangkitan COVID-19 menular melalui titisan air liur atau pernafasan dan boleh menyebabkan spektrum simptom jangkitan yang luas dari ringan hingga kritikal termasuklah kegagalan organ, dengan kadar kematian melebihi 2.3%.

Selain ubat-ubatan dalam kajian, masih tidak ada ubat khusus atau vaksin yang sedia ada atau terbukti berkesan. Anda serta mereka yang sembuh dari infeksi COVID-19 ini, disebabkan badan anda telah berjaya melawan penyakit berkenaan dan sekarang dalam darah anda mempunyai faktor-faktor yang mampu melawan virus COVID-19.

Convalescent plasma (CP) merupakan strategi rawatan yang berpotensi untuk *novel coronavirus* dan cara rawatan ini telah digunakan dalam beberapa jangkitan seperti SARS, MERS, and Ebola virus disease (EVD), dimana masih tiada antiviral yang berkesan.

Kenapa saya dipilih untuk melalui prosedur ini?

Kami berpendapat bahawa sesetengah pesakit yang sedang mengalami jangkitan mungkin lebih cenderung pulih jika mereka menerima sebahagian daripada plasma anda (bahagian cecair darah anda). Walaubagaimanapun, kami tiada kepastian. Masih ada kemungkinan juga pesakit COVID-19 tidak dapat pulih, walaupun selepas menerima plasma anda. Oleh kerana, kami tiada pilihan rawatan yang terbukti berkesan pada masa kini, kami ingin mencubanya, dengan kemungkinan ia berjaya, kerana telah terbukti berkesan dengan virus-virus lain. Anda boleh melihat ianya sebagai hadiah kepada orang lain.

Namun demikian, perlu diingatkan pendermaan darah, termasuk pendermaan plasma, adalah secara sukarela dan tidak dibayar di Malaysia. Anda juga tidak terpaksa menderma plasma jika anda tidak bersetuju.

Apakan langkah persediaannya?

Kami akan meminta kebenaran anda untuk menyemak rekod perubatan anda dari hospital yang merawat anda untuk COVID-19, bagi tujuan untuk menilai sama ada anda boleh menderma plasma dengan selamat.

Sekiranya anda bersetuju untuk menderma plasma untuk rawatan COVID-19, kami akan mengambil sedikit darah anda (32ml) untuk memeriksa jenis darah anda dan sama ada darah anda boleh digunakan untuk rawatan COVID-19.

Jika hemoglobin anda terlalu rendah atau jika anda tidak dapat menderma kerana apa-apa sebab, kami tidak akan meneruskan dan akan menerangkan kepada anda jika ada pemeriksaab perubatan susulan diperlukan. Walau bagaimanapun, jika anda sesuai untuk derma, kami akan menetapkan tarikh dan masa yang sesuai untuk menderma.

Bagaimana prosedur ini dijalankan?

Untuk pendermaan plasma, anda perlu datang ke pusat pendermaan. Di sana, jururawat yang berpengalaman akan memasukkan jarum ke dalam salur darah anda setelah diberikan bius lokal. Jarum ini digunakan untuk mengeluarkan darah anda ke dalam mesin yang boleh mengasingkan plasma daripada bahagian selular darah. Setelah diasingkan, sel-sel darah akan dipulangkan melalui jarum yang sama. Untuk mengelakkan darah dari membeku, pencair darah atau anti-koagulan, akan dicampurkan dengan darah secara automatik ketika darah masuk ke dalam mesin. Prosedur untuk mengumpul kira-kira 500mls (anggaran botol air mineral yang kecil), dijangkakan mengambil masa kira-kira 30-45minit.

Apakah risiko dan komplikasi prosedur ini?

Pengambilan darah dari lengan mungkin boleh menyebabkan lebam, sakit ringan atau ketidakselesaan dan sangat jarang, jangkitan. Kami akan mengambil semua langkah berjaga-jaga untuk mengurangkan risiko ini.

Perubahan tekanan darah. Sesetengah orang mungkin berasa ringan kepala atau pening apabila jarum dimasukkan ke dalam salur darah mereka, semasa atau selepas pendermaan plasma. Ini berlangsung selama beberapa minit dan akan kembali pulih. Anda akan dipantau dengan teliti sepanjang prosedur dan digalakkan untuk meminum banyak air pada akhir prosedur.

Kadar kalsium rendah. Ini biasanya disebabkan oleh anti-koagulan yang digunakan. Gejala termasuklah sensasi kesemutan di sekeliling mulut dan jari mereka. Sesetengah penderma mungkin mengalami kekejangan otot. Sila maklumkan kepada jururawat sekiranya ada gejala berkenaan. Anda akan diberi beberapa tablet suplemen kalsium.

Komplikasi teruk lain seperti pemecahan sel-sel merah, abnormaliti dengupan jantung atau perubahan tekanan darah yang teruk hingga perlu dimasukkan ke hospital adalah jarang berlaku. Secara keseluruhannya, ia adalah prosedur yang selamat bagi majoriti penderma.

Apa langkah seterusnya setelah pendermaan plasma?

Anda akan diberikan hidangan ringan selepas prosedur. Selepas berehat 15-30 minit, anda boleh kembali ke aktiviti biasa tetapi cuba dinasihatkan untuk menghindari aktiviti berat sepanjang hari. Anda harus minum banyak air selama 24 jam berikutnya. Badan anda akan menggantikan cairan yang hilang dalam masa 36 jam.

Plasma yang telah didermakan akan disimpan di dalam peti sejuk khas. Ia tidak akan mempunyai nama anda di atasnya. Apabila terdapat pesakit dengan COVID-19 yang mungkin dapat dirawat dengan plasma yang didermakan oleh anda, ia akan dikeluarkan dari stok, dibawa ke suhu bilik, dan diberikan kepada pesakit melalui salur darah. Kami akan memantau pesakit dan menrekodkan kesemuanya, supaya kami dapat belajar dari pengalaman ini, dan mengetahui lebih lanjut mengenai penggunaan plasma untuk rawatan COVID-19.

Apakah pilihan lain?

Tidak berkaitan

Apa akan jadi jika saya tidak menderma?

Anda bebas membuat keputusan sama ada anda ingin menderma darah/plasma atau tidak. Jika anda tidak memenuhi kriteria pendermaan darah, anda akan dimaklumkan oleh doktor yang bertanggungjawab.

Anda berhak untuk membatalkan pendermaan darah/plasma anda walaupun anda telah menderma sehingga sebelum daraha/plasma ditransfusikan kepada pesakit dengan memberitahu doktor yang bertanggungjawab. Setelah diberikan kepada pesakit, anda tidak boleh lagi membuat permintaan ini.

Keputusan anda untuk membatalkan pendermaan darah/plasma selagi sebelum diberikan kepada pesakit, tidak akan menjejaskan penjagaan masa depan anda.

Soalan-soalan lain oleh penderma

Confidentiality

Sebarang maklumat yang diberikan dan semua keputusan ujian akan dirahsiakan. Kakitangan perubatan yang menguji darah anda mempunyai tanggungjawab untuk memaklumkan kepada anda tentang semua keputusan ujian darah, dan memberi nasihat tentang sebarang rawatan yang diperlukan.

Siapa pesakit yang akan menerima darah/plasma saya?

Pesakit COVID-19 akan menerima plasma yang didermakan oleh anda, tetapi sukar untuk diramalkan siapa yang akan menerimanya. Pesakit mestilah mempunyai jenis darah yang serasi dengan darah anda. Plasma yang didermakan akan mempunyai nombor pendermaan yang unik dan bukan nama anda, jadi tidak ada yang tahu siapa akan menerima plasma yang telah didermakan. Yang pasti ia akan digunakan untuk pesakit yang memerlukannya, dan semua maklumat mengenai anda dan sumbangan anda akan tetap dirahsiakan.

Adakah pesakit yang menerima darah/plasma tahu siapa pendermanya?

Tidak seorang pun, termasuk pesakit yang menerima darah/plasma anda akan tahu siapa yang telah mendermakannya. Ini bertujuan untuk melindungi privasi anda. Yakinlah bahawa darah/plasma yang telah didermakan amat dihargai.

Perbelanjaan dan pembayaran

Tidak akan ada sebarang bayaran dikenakan berkaitan dengan pendermaan ini. Anda juga tidak akan dibayar untuk pendermaan ini. Jika anda mempunyai sebarang pertanyaan, sila hubungi Pusat Darah Negara (Phone: 03-26132688)

	Nama: No K/P: Tarikh lahir::
Maklumat prosedur berkaitan pendermaan <i>convalescent plasma</i> untuk merawat infeksi COVID-19.	Bangsa: Jantina: No kes:

Persetujuan

Bahagian I- Diisi oleh Ibu Bapa/ Penjaga

Saya akui telah menerima lembaran maklumat prosedur ini.

Saya akui komplikasi yang disenaraikan adalah tidak lengkap.

Saya faham yang saya telah diberi peluang untuk bertanya dengan lebih lanjut berkaitan prosedur ini.

Diakui oleh:

.....
 *Tandatangan/Cap ibu jari kanan

.....
 Tarikh

.....
 Nama, tandatangan dan No. K/P Ibu Bapa/ Penjaga

Bahagian II-Diisi oleh Pengamal Perubatan dan saksi

Saya mengesahkan bahawa saya telah menjelaskan sebab dan jenis prosedur serta komplikasi yang berkemungkinan boleh disebabkan dari prosedur ini kepada pesakit / penjaga yang sah.

.....
 Nama, tandatangan dan No. K/P Pegawai Perubatan/Pakar

.....
 Tarikh

Bahagian III- Diisi oleh Pihak Perubatan Transfusi

Saya mengesahkan bahawa saya telah menjelaskan sebab dan jenis prosedur serta komplikasi yang berkemungkinan boleh disebabkan dari prosedur ini kepada pesakit / penjaga yang sah.

.....
 Nama, tandatangan dan No. K/P Pegawai Perubatan/Pakar

.....
 Tarikh

Requirements of samples for CP Donor

1. For other pre-referral investigations by referring hospitals (listed below), to follow requirement of own hospital's laboratory
 - Transfusion Transmitted Infection (TTI) screening for HIV, Hepatitis B, Hepatitis C and syphilis
 - COVID-19 antibody test
 - Full Blood Count and liver function test: albumin, total protein, serum calcium (if available)

2. Anti HLA typing (in multiparous women ONLY to prevent occurrence of TRALI) to PDN
 - 6-8 mls in plain tube and EDTA tube
 - To be sent to PDN
 - Using PERPAT 301 form or and Haematology/Serology Request Form (PDN/HA/QP-01/01)
 - TAT for Anti HLA typing : 10 working days

REFERRAL LETTER FOR CONVALESCENT PLASMA DONOR

To:

Date:

Transfusion Medicine Specialist

National Blood Center, Kuala Lumpur

Patient's name			
Identification number			
Age			
Gender			
Date of COVID-19 diagnosis			
Date of PCR negative	1 st :	2 nd :	3 rd :
Date of recovery			
Relevant clinical histories	Past medical history:		
	Admission summary:		
Obstetric history (for female donor)			
Blood group (if available)	ABO:	Rh(D):	Red cell antibodies:
Full blood count	Hb:	Plt:	WBC:
Biochemistry test	Calcium(if available):	Albumin:	Total protein:
COVID-19 antibody titration (if available)			Anti-HLA (if available)
Transfusion transmitted infection screening	HIV:		Hepatitis B:
	Hepatitis C:		Syphilis:

Kindly see him / her and do the needful. Thank you.

Yours sincerely,

 (Dr's name, designation, hospital)

Appendix 5: Donor Registration and Consent Form



**BLOOD DONOR REGISTRATION FORM
BLOOD TRANSFUSION SERVICE
MINISTRY OF HEALTH MALAYSIA**



(Collection Centre)

Name	:	_____			
New IC No.	:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<div style="border: 1px solid black; padding: 5px;"> For Non-Citizen Only Passport No : _____ Country : _____ </div>		
Police/Amy IC No.	:	<input type="text"/>			
Date of Birth	:	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>			
Age	:	<input type="text"/> <input type="text"/> Years Old	Gender :	<input type="checkbox"/> Male <input type="checkbox"/> Female	
Ethnicity	:	<input type="checkbox"/> Malay	<input type="checkbox"/> Chinese	<input type="checkbox"/> Indian	<input type="checkbox"/> Others (specify) _____
		<input type="checkbox"/> Iban	<input type="checkbox"/> Kadazan	<input type="checkbox"/> Melanau	
		<input type="checkbox"/> Murut	<input type="checkbox"/> Bidayuh	<input type="checkbox"/> Bajau	
Marital Status	:	<input type="checkbox"/> Single	<input type="checkbox"/> Married	<input type="checkbox"/> Widowed/Divorced	
Occupation	:	_____		E-mail :	_____
Home Tel. No.	:	_____		H/P No. :	_____
Office Tel No.	:	_____		Fax :	_____
Current Home Address	:	_____			
		State :	_____	Postcode :	_____
Postal Address	:	_____			
		State :	_____	Postcode :	_____

ATTENTION : IS YOUR BLOOD SAFE TO BE DONATED?

Thank you for volunteering to donate your blood. The blood that you donate could help save lives.

We always strive to ensure that the blood given to patients is safe. For that, all donated blood is tested for evidence of infections by Hepatitis B and C, HIV and Syphilis. However, occasionally these tests are unable to detect blood that has only recently being infected. As a result, the infected blood may unknowingly end up being given to patients.

Therefore, in order to help us ensure that the blood donated is safe for transfusion, you are requested to carefully read the statement below before donating your blood.

You are ASKED NOT TO DONATE BLOOD if you:

- know or suspect you may have HIV, suffering from/carrier of Hepatitis B or Hepatitis C, or being infected with Syphilis or other Sexually Transmitted Disease (STD)
- lead or had led a life style involving **CHANGING MULTIPLE SEXUAL PARTNERS**
- are a man who have had sex with another man (**HOMOSEXUAL/BISEXUAL**)
- have ever made payment or received payment for having sex
- have had sex with commercial sex worker (prostitute)
- have had taken illegal drugs intravenously
- have ever had sex with anyone from any of the above group

You are also asked **NOT TO** donate just to test your blood. Blood test can be performed at any nearby Health Clinic. If you have any questions, do not hesitate to ask our Medical Officer on duty for help.

"SAFE BLOOD BEGINS WITH ME"

BLOOD DONOR ELIGIBILITY QUESTIONNAIRES

"Any blood donor who is found to make false declaration pertaining to his or her high risk lifestyle behaviours will be prosecuted in Court under the existing laws"

Before you proceed with the questionnaires, please read and understand the statement on the front page. Answer the following questions by ticking ✓ in the appropriate boxes.

	Yes	No														
1. Are you feeling healthy and well today?	<input type="checkbox"/>	<input type="checkbox"/>														
2. Are you donating today to test your blood for HIV, Hepatitis and/or Syphilis?	<input type="checkbox"/>	<input type="checkbox"/>														
3. Have you donated blood before? If yes, have you had any problem during or after the donation? If yes, please specify _____	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>														
4. In the past one week, have you: a) Taken any medication? If yes, please specify _____ b) Suffered from fever, cold and/or cough? c) Suffered from headache or migraine? d) Seek treatment from a doctor for any health problem? If yes, please specify _____	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>														
5. Are you suffering from / have ever suffered from / undergoing treatment for / had been treated for any of the following health problems?	Yes	No														
<ul style="list-style-type: none"> • Jaundice • Hepatitis B or Hepatitis C • HIV • STDs / Syphilis • Malaria • Renal Disease / Renal Failure • Asthma 	<table border="0"> <tr><td style="text-align: center;">Yes</td><td style="text-align: center;">No</td></tr> <tr><td style="text-align: center;"><input type="checkbox"/></td><td style="text-align: center;"><input type="checkbox"/></td></tr> </table>	Yes	No	<input type="checkbox"/>	<ul style="list-style-type: none"> • Tuberculosis • Diabetes • Hypertension • Heart Disease • Mental Illness • Epilepsy • Others* 											
Yes	No															
<input type="checkbox"/>	<input type="checkbox"/>															
<input type="checkbox"/>	<input type="checkbox"/>															
<input type="checkbox"/>	<input type="checkbox"/>															
<input type="checkbox"/>	<input type="checkbox"/>															
<input type="checkbox"/>	<input type="checkbox"/>															
<input type="checkbox"/>	<input type="checkbox"/>															
*If yes, please specify _____	<input type="checkbox"/>	<input type="checkbox"/>														
6. Has anybody in your family been diagnosed with or currently being treated for Hepatitis B or Hepatitis C? If yes, please state your relationship with him/her _____	<input type="checkbox"/>	<input type="checkbox"/>														
7. In the last 6 months, have you : a) Underwent any surgical procedure or operation? b) Received any blood transfusion? c) Had any accidental needle stick injury?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>														
8. Have you received any immunisation injection or any type of injection for beauty (e.g. botox, collagen) within the past 4 weeks? If yes, please specify type and/or purpose _____	<input type="checkbox"/>	<input type="checkbox"/>														
9. Have you had any dental treatment in the past 24 hours?	<input type="checkbox"/>	<input type="checkbox"/>														
10. Have you had any body piercing, tattooing, blood-letting / cupping (<i>berbekam</i>) or acupuncture done within the past 6 months?	<input type="checkbox"/>	<input type="checkbox"/>														
11. In the past 24 hours, have you taken any alcoholic drink until you were drunk or intoxicated?	<input type="checkbox"/>	<input type="checkbox"/>														
12. Have you ever received: a) Injection with human growth hormone? b) Cornea transplant? c) Brain membrane (duramater) transplant? d) Bone marrow or stem cell transplant?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>														

- | | |
|---|---|
| 13. Risk of infection with variant Creutzfeldt-Jakob Disease (vCJD) | Yes No |
| a) Have you ever visited or lived in the United Kingdom (England, Northern Ireland, Ireland, Wales, Scotland, the Isle of Man, the Channel Island) or the Republic of Ireland for a cumulative period of 6 months or more between 1st January 1980 and 31st December 1996? | <input type="checkbox"/> <input type="checkbox"/> |
| b) Have you ever received a transfusion or injection of blood or blood product while in the United Kingdom between 1st January 1980 until now? | <input type="checkbox"/> <input type="checkbox"/> |
| c) Have you ever visited or lived in the following European countries* for a cumulative period of 5 years or more between 1st January 1980 until now?
(*Austria, Belgium, Denmark, Finland, France, Germany, Greece, Holland, Italy, Liechtenstein, Luxembourg, Norway, Portugal, Spain, Sweden and Switzerland) | <input type="checkbox"/> <input type="checkbox"/> |

14. For patient safety, the following questions **SHALL** be answered **HONESTLY**, even if you were only involved in it once. You are required to answer the following questions in front of the assigned doctor or officer from MOH who interviews you.

- | | | |
|---|--------------------------|--------------------------|
| | Yes | No |
| a) If you are a man, have you ever had sex with another man? | <input type="checkbox"/> | <input type="checkbox"/> |
| b) Have you ever had sex with commercial sex worker /prostitute? | <input type="checkbox"/> | <input type="checkbox"/> |
| c) Have you ever paid or received payment in exchange for sex? | <input type="checkbox"/> | <input type="checkbox"/> |
| d) Have you ever had more than one sexual partner? | <input type="checkbox"/> | <input type="checkbox"/> |
| e) Have you had any new sexual partner(s) within the past 12 months? | <input type="checkbox"/> | <input type="checkbox"/> |
| f) Have you ever injected yourself with illegal drugs, including drugs for body building? | <input type="checkbox"/> | <input type="checkbox"/> |
| g) Does your sexual partner belong to any of the above categories? | <input type="checkbox"/> | <input type="checkbox"/> |
| h) Have you or your sexual partner ever been tested positive for HIV? | <input type="checkbox"/> | <input type="checkbox"/> |
| i) Do you think you or your sexual partner may be tested positive for HIV? | <input type="checkbox"/> | <input type="checkbox"/> |

I, name as stated on this form, hereby confirm that I understand ALL the above questions as EXPLAINED to me and I DECLARE that I have answered them TRUTHFULLY and SINCERELY.

(Donor's Signature)
Date : _____

(Interviewer's Name & Signature)
Date : _____

- | | |
|--|---|
| 15. To be answered by female donors only | Yes No |
| a) Are you having your menstrual period? | <input type="checkbox"/> <input type="checkbox"/> |
| b) Are you pregnant or may be pregnant? | <input type="checkbox"/> <input type="checkbox"/> |
| c) Do you have a child that is still breast-feeding? | <input type="checkbox"/> <input type="checkbox"/> |
| d) Have you given birth or had a miscarriage in the past 6 months? | <input type="checkbox"/> <input type="checkbox"/> |

DONOR DECLARATION AND CONSENT

(to be signed in front of the MOH's doctor or staff who interviews you)

I, name as stated on this form:-

- Declare that the answers to ALL of the above questions are true.
- Realise that I shall not donate my blood if I belong to any of the groups of individuals at risk of contracting HIV/Hepatitis/Syphilis (refer to ATTENTION on page 1).
- Voluntarily give permission for my blood/blood component to be withdrawn and used in testing for HIV, Hepatitis B, Hepatitis C and Syphilis, and in what other manner deemed appropriate by the Blood Service Centre, Hospital and the Ministry of Health, Malaysia.
- Understand that all information given and the test results will be kept confidential.

(Donor's Signature)
Date : _____

(Interviewer's Name & Signature)
Date : _____

TO BE FILLED IN BY MOH'S STAFF ON DUTY

Donation Identification Number (Barcode): _____

Type of Donor : New Donor
 Regular/Repeat Donor
 Lapsed Donor
 Autologous Donor

Last Donation Date : / /

Total Donation : _____

Donor Eligibility Status (e.g. SUKUSA, BBIS) :

Eligible Not Eligible

Registration Date : / /

Registered By : _____
 (Staff's Name & Signature)

Observation / Tests	Results	Staff's Name & Signature
Body Weight (kg)		
Blood Group		
Hb Level (g/dL) (*please state where appropriate)	<input type="checkbox"/> ≥ 12.5 g/dL <input type="checkbox"/> < 12.5 g/dL *Hb value : _____ g/dL	
Pre-donation Platelet Count (apheresis platelet donation)	_____ x 10 ⁹ /L	
Blood Pressure (mmHg)		

The individual named on this form has been interviewed, examined and tested, and is found to be:
 (please mark ✓)

ELIGIBLE TO DONATE

NOT ELIGIBLE TO DONATE

Whole Blood Apheresis
 Triple Bag Plasma
 Double Bag Platelet
 Single Bag Others (specify) _____
 Filter Bag

Reason : _____

Deferral Status :

Permanent
 Temporary

Duration : _____

Volume : ml

Staff's Name & Initial : _____

Blood Donation Process		Staff's Name & Signature
Venepuncture Performs By :	<input type="text"/>	
Anaesthetic Given? :	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Time Donation Start :	Time Start : <input type="text"/>	
Sample Taken? :	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Time Donation End :	Time End : <input type="text"/>	
Remaining Barcodes (Donation Identification) :	Total : _____ <i>Paste Remaining Barcodes Here</i>	
Notes / Comment (if any) :		

Monitoring of Transfusion Recipient of COVID -19 Convalescent Plasma

NAME :

AGE :

IDENTITY CARD (IC) NUMBER :

RN NUMBER :

COMORBIDS OF PATIENT :

WARD :

HOSPITAL :

DATE OF ADMISSION:

DATE OF POSITIVE PCR FOR COVID -19 :

CLINICAL STAGE DURING DIAGNOSIS :

DATE OF STARTING CONVALESCENT PLASMA :

CLINICAL STAGE DURING RECEIVING CONVALESCENT PLASMA :

LIST OF MEDICATIONS PRESCRIBED :

<p>List Of Anti Viral prescribed</p>	<ol style="list-style-type: none"> 1. 2. 3. 4. 5.
<p>List of another supportive medicine (eg : steroids, IV Immunoglobulin)</p>	<ol style="list-style-type: none"> 1. 2. 3. 4. 5.

PATIENTS PROGRESS AFTER CONVALESCENT PLASMA TRANSFUSION

	PRE TRANSFUSION	DAY 1	DAY 3	DAY 5	DAY 7	DAY 12
A) Clinical Characteristic						
• Temperature						
• PAO2/FIO2						
• Mechanical Ventilation						
B) Chest X ray/CT scan findings						
C) Lab Findings						
• C-reactive protein						
• Procalcitonin						
• Other test (CRP/LFT/RP/co ag)						
D) Development of tranfusion reaction (if any)						

ICU LENGTH OF STAY :

HOSPITAL LENGTH OF STAY :

DISCHARGE FROM ICU :

DISCHARGE FROM HOSPITAL:

DATE OF PCR FOR COVID -19 NEGATIVE :

MORTALITY : YES / NO

